Remarks

After entry of the amendment, claims 21-40 are pending in the application.

Claims 1-20 have been canceled without prejudice.

Claims 21-40 are supported by the originally filed claims and the specification at, for example, page 1, lines 19-21; page 2, lines 9-12; and page 3, lines 7-25.

No issues of new matter should arise and entry of the amendment is respectfully requested.

Rejection under 35 USC § 102(b)

Claims 6, 7, 10, 15, 16, 19 and 20 are rejected under 35 USC § 102(b) as being anticipated by Henneberg, *J. Neural. Transm.*, 106(3-4), XXV-XXVI (April, 1999).

Henneberg is not prior art under § 102(b). The present application has a priority date of March 3, 2000. Henneberg was publish in April 1999, i.e., less than one year before the priority date of the present application. Assuming Henneberg is prior art, Henneberg would be prior art under § 102(a).

Applicant respectfully submits that Henneberg has not been peer reviewed and has not been statistically analyzed. Henneberg further admits that the report is based on subjective criteria, and that no objective criteria were used for the study.

There is no evidence of record that the patients in Henneberg's study did not suffer from Alzheimer's dementia in a manner wholly unrelated to Parkinson's disease. Henneberg has not established a connection between dementia and Parkinson's disease, and there is no evidence that the patients' in Henneberg's study suffered from dementia that was caused by Parkinson's disease. There is no evidence that Henneberg was treating Parkinson's dementia.

In view of the above, Applicant respectfully requests that the rejection of claims 6, 7, 10, 15, 16, 19 and 20 be withdrawn.

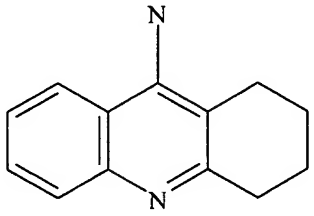
Rejection under 35 USC § 103

Claims 1-20 are rejected under 35 USC §103 as being obvious over Hutchinson (US Patent No. 5,965,571) in view of Sugimoto et al (US Patent No. 4,895,841) and Henneberg, *J. Neural. Transm.*, 106(3-4), XXV-XXVI (April, 1999).

Applicant respectfully traverses the rejection.

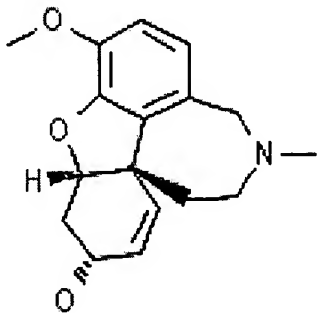
Hutchinson is not relevant to the claimed invention. Hutchinson discloses certain compounds (i.e., galanthamine, physostigmine, tacrine, citicoline, velnacrine maleate, metrifonate, and heptastigmine) as allegedly being useful for treating Parkinson's disease. Hutchinson provides one example of the use of tacrine to treat Parkinson's disease.

The chemical structure of tacrine, the only compound exemplified in Hutchinson, is:



The chemical structure of tacrine is wholly unrelated to the chemical structure of the claimed compound donepezil. There is no evidence that tacrine and donepezil have the same cholinesterase inhibiting activity. Moreover, tacrine and donepezil may have other properties (e.g., mechanisms of action; selectivity; pharmacokinetic properties, pharmacodynamic properties) which support their activity. The PTO has made a blanket assumption that any compound identified as "a cholinesterase inhibitor" would have the same activity and would not have any other properties to support their function. The PTO has not provided any evidence to support these assumptions.

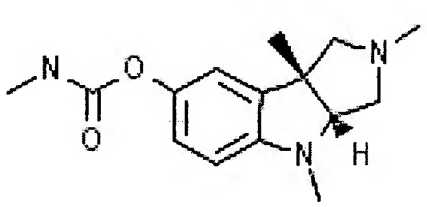
The chemical structure of galanthamine is



The chemical structure of galanthamine is wholly unrelated to the chemical structure of the claimed compound donepezil. There is no evidence that galanthamine and donepezil have the

same cholinesterase inhibiting activity. Moreover, galanthamine and donepezil may have other properties (e.g., mechanisms of action; selectivity; pharmacokinetic properties, pharmacodynamic properties) which support their activity. The PTO has made a blanket assumption that any compound identified as "a cholinesterase inhibitor" would have the same activity and would not have any other properties to support their function. The PTO has not provided any evidence to support these assumptions.

The chemical structure of physostigmine is:

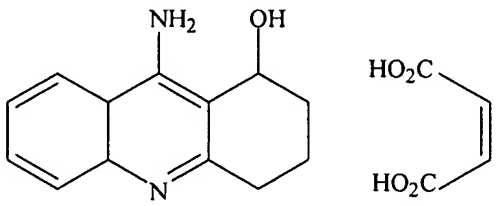


The chemical structure of physostigmine is wholly unrelated to the chemical structure of the claimed compound donepezil. There is no evidence that physostigmine and donepezil have the same cholinesterase inhibiting activity. Moreover, physostigmine and donepezil may have other properties (e.g., mechanisms of action; selectivity; pharmacokinetic properties, pharmacodynamic properties) which support their activity. The PTO has made a blanket assumption that any compound identified as "a cholinesterase inhibitor" would have the same activity and would not have any other properties to support their function. The PTO has not provided any evidence to support these assumptions.

Citicoline is a pyrimidine nucleotide having a chemical structure similar to cytidine. The chemical structure of citicoline is wholly unrelated to the chemical structure of the claimed compound donepezil. There is no evidence that citicoline and donepezil have the same cholinesterase inhibiting activity. Moreover, citicoline and donepezil may have other properties (e.g., mechanisms of action; selectivity; pharmacokinetic properties, pharmacodynamic properties) which support their activity. The PTO has made a blanket

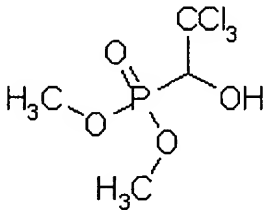
assumption that any compound identified as "a cholinesterase inhibitor" would have the same activity and would not have any other properties to support their function. The PTO has not provided any evidence to support these assumptions.

The chemical structure of velnacrine maleate is:



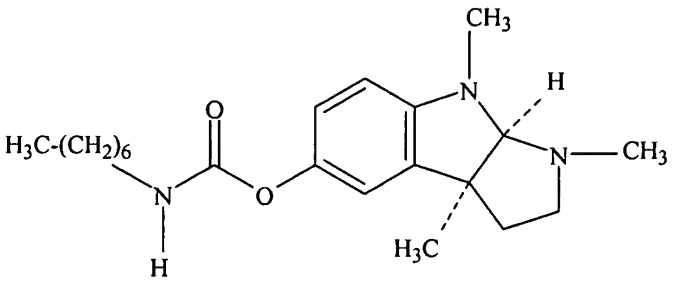
The chemical structure of velnacrine maleate is wholly unrelated to the chemical structure of the claimed compound donepezil. There is no evidence that velnacrine maleate and donepezil have the same cholinesterase inhibiting activity. Moreover, velnacrine maleate and donepezil may have other properties (e.g., mechanisms of action; selectivity; pharmacokinetic properties, pharmacodynamic properties) which support their activity. The PTO has made a blanket assumption that any compound identified as "a cholinesterase inhibitor" would have the same activity and would not have any other properties to support their function. The PTO has not provided any evidence to support these assumptions.

The chemical structure of metrifonate is:



The chemical structure of metrifonate is wholly unrelated to the chemical structure of the claimed compound donepezil. There is no evidence that metrifonate and donepezil have the same cholinesterase inhibiting activity. Moreover, metrifonate and donepezil may have other properties (e.g., mechanisms of action; selectivity; pharmacokinetic properties, pharmacodynamic properties) which support their activity. The PTO has made a blanket assumption that any compound identified as "a cholinesterase inhibitor" would have the same activity and would not have any other properties to support their function. The PTO has not provided any evidence to support these assumptions.

The chemical structure of heptastigmine, which is the same as the chemical structure of epastigmine, is:



The chemical structure of heptastigmine (i.e., epastigmine) is wholly unrelated to the chemical structure of the claimed compound donepezil. There is no evidence that heptastigmine and donepezil have the same cholinesterase inhibiting activity. Moreover, heptastigmine and donepezil may have other properties (e.g., mechanisms of action; selectivity; pharmacokinetic properties, pharmacodynamic properties) which support their activity. The PTO has made a blanket assumption that any compound identified as "a cholinesterase inhibitor" would have the same activity and would not have any other properties to support their function. The PTO has not provided any evidence to support these assumptions.

In view of the above analysis, Applicant respectfully submits that Hutchinson does not disclose or suggest donepezil; does not disclose or suggest any chemical compounds with a chemical structure that is remotely similar to donepezil; has not shown any relationship between the acetylcholinesterase inhibitory activity of any of the compounds; and has not provided any evidence that the compounds produce their effects in the same ways, including for example, mechanisms of action; selectivities; pharmacokinetic properties, and pharmacodynamic properties. Without such evidence, Hutchinson cannot form the basis for rejecting the pending claims.

Similarly, Sugimoto is unrelated to the claimed invention. Sugimoto teaches donepezil, but does not disclose or suggest that donepezil could be useful for treating dementia caused by Parkinson's disease. The PTO's rejection is based on a sentence in Sugimoto that states the compounds may be "effective for the treatment of various kinds of

dementia." There is no evidence that donepezil would be useful for dementia caused by Parkinson's disease, particularly in view of the teachings in Hutchinson discussed above.

Because two of the three cited references are unrelated to the claimed invention and because Henneberg does not cure the deficiencies of these references, the rejection cannot be maintained. In view thereof, Applicant respectfully requests that the rejection of claims 1-20 be withdrawn.

Rejection under 35 USC § 103

Claims 1-20 are rejected under 35 USC § 103 as being obvious over Henneberg, *J. Neural. Transm.*, 106(3-4), XXV-XXVI (April, 1999) in view of Sugimoto et al (US Patent No. 4,895,841).

Applicant respectfully traverses the rejection.

As discussed in the preceding rejection, Sugimoto is unrelated to the claimed invention. Sugimoto teaches donepezil, but does not disclose or suggest that donepezil could be useful for treating dementia caused by Parkinson's disease. The PTO's rejection is based on a sentence in Sugimoto that states the compounds may be "effective for the treatment of various kinds of dementia." There is no evidence that donepezil would be useful for dementia caused by Parkinson's disease, as evidenced by the teachings in US Patent No. 5,965,571 to Hutchinson, as discussed above.

Sugimoto does not cure the deficiencies of Henneberg and provides no motivation, suggestion, or reasonable expectation of success to arrive at the claimed invention. Accordingly, the rejection cannot be maintained. In view thereof, Applicant respectfully requests that the rejection of claims 1-20 be withdrawn.

Rejection under 35 USC § 103

Claims 1-14 are rejected under 35 USC § 103 as being obvious over Gregor (US Patent No. 5,486,512) in view of Sugimoto et al (US Patent No. 4,895,841) and Henneberg, *J. Neural. Transm.* (1999).

Applicant respectfully traverses the rejection.

Gregor is wholly unrelated to the claimed invention. Gregor describes compounds that are quinazoline derivatives, i.e., compounds that have a 6-membered carbocyclic ring fused to a 6-membered heterocyclic ring, wherein the heterocyclic ring contains 2 nitrogen

atoms and has the structure N=C-N.

The claimed invention is directed to compounds that are structurally unrelated to the compounds described by Gregor. There is no evidence that the claimed compounds would possess the same properties or characteristics as the structurally unrelated compounds described by Gregor. Moreover, Gregor does not disclose or suggest the use of the claimed compounds for treating Parkinson's disease or for treating dementia caused by Parkinson's disease.

The claimed invention is directed to donepezil, which has a six-membered carbocyclic ring fused to a five-membered carbocyclic ring. Donepezil is structurally unrelated to the compounds described by Gregor. There is no evidence that these structurally unrelated compounds would possess the same properties or characteristics as the compounds described by Gregor. Moreover, Gregor does not disclose or suggest the use of the claimed compounds for treating the claimed diseases.

There is no evidence of record that Gregor could be used to treat any other diseases than those specifically described by Gregor. Moreover, there is no evidence that structurally unrelated compounds, such as those presently claimed, could be used to treat any of the diseases described by Gregor.

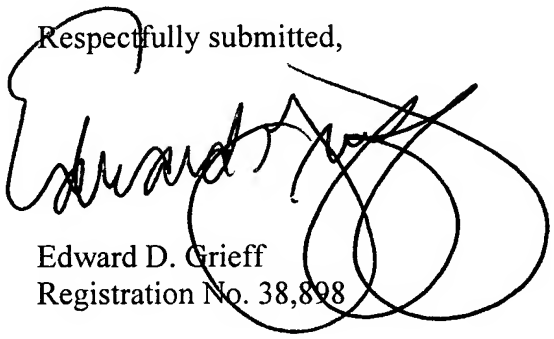
Sugimoto does not cure the deficiencies of Gregor. There is no motivation, suggestion or reasonable expectation of success to combine two references that describe compounds with wholly unrelated chemical structures and that do not disclose or suggest methods for treating dementia caused by Parkinson's disease. As discussed in the preceding two rejections, Sugimoto is unrelated to the claimed invention. Sugimoto teaches donepezil, but does not disclose or suggest that donepezil could be useful for treating dementia caused by Parkinson's disease. The PTO's rejection is based on a sentence in Sugimoto that states the compounds may be "effective for the treatment of various kinds of dementia." There is no evidence that donepezil would be useful for dementia caused by Parkinson's disease, as evidenced by the teachings in US Patent No. 5,965,571 to Hutchinson, as discussed above.

Because neither Gregor nor Sugimoto is related to the claimed invention, the rejection cannot be maintained. In view thereof, Applicant respectfully requests that the rejection of claims 1-14 be withdrawn.

Summary

Applicant respectfully requests an early and favorable reconsideration and allowance of claims 21-40.

Respectfully submitted,



Edward D. Grieff
Registration No. 38,898

Date: November 20, 2006

Venable LLP
575 7th Street, NW
Washington, DC 20004
Phone: 202-344-4382
Fax: 202-344-8300